# Report to the U.S. EPA Scientific Integrity Review Panel regarding the (b) (6) Allegation

July 28, 2015

#### Background

The U.S. Environmental Protection Agency (EPA) is dedicated to preserving the integrity of the scientific and scholarly activities it conducts and that are conducted on its behalf. The EPA Scientific Integrity Policy, dated February 2012, provides principles and standards to ensure scientific integrity in the use, conduct, and communication of science. When this policy is not adhered to, or is circumvented, the robustness of EPA science and the trust in the results of our scientific work can be impacted, causing a loss of scientific integrity. Loss of scientific integrity is the result of a deliberate action by an employee that compromises the conduct, production, or use of scientific and scholarly activities and assessments. EPA does not tolerate loss of integrity in the performance of scientific and scholarly activities or in the application of science in decision making.

## Procedures for Resolving Allegations of a Loss of Scientific Integrity

Allegations of the loss of scientific or scholarly integrity are submitted to the EPA's Scientific Integrity Official (ScIO). Three criteria are necessary to establish a loss of integrity:

- There is a significant departure from accepted practices of the relevant scientific or scholarly community,
- 2) The actions causing the loss of integrity are committed intentionally, knowingly or recklessly, and
- 3) The allegation is proven by a preponderance of evidence.

If there is a reasonable basis to believe the allegation may have merit, a Scientific Integrity Review Panel, comprised of the ScIO, the relevant Deputy Scientific Integrity Official (DScIO), and an impartial DScIO provide a review of the science and any other relevant information and reach a majority consensus.

#### Allegation

(b) (6)
("Study") for research misconduct. (b) (6)
(b) (6)
(claimed that the study's design was flawed, the authors fabricated and falsified information, the results did not support the conclusions, and that the authors had engaged in plagiarism. (b) (6)
(b) (claimed that the Study be retracted. The OIG found that the allegation did not rise to the level of criminal charges of research misconduct and referred the case to Dr. Francesca T. Grifo, the EPA ScIO.

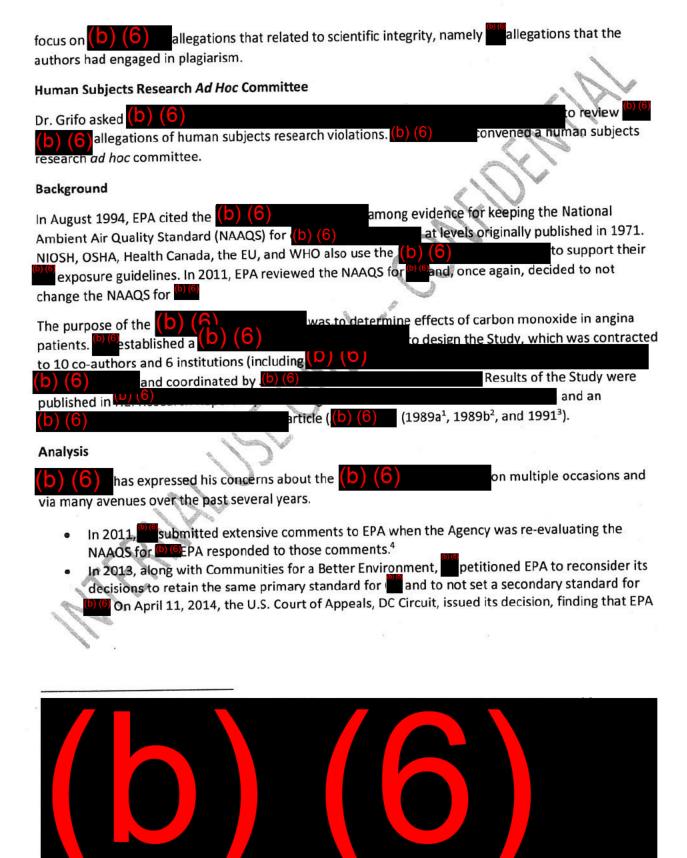
### Scientific Integrity Review Panel

A Scientific Integrity Review Panel (SIRP) comprised of Dr. Grifo (the SciO) (b) (6)

(b) (6)

was convened to review the relevant information on the case. Most of (b) (6)

claims were related to research misconduct, a charge that the OIG declined to pursue. The SIRP should



standing to challenge EPA's decision not to set a secondary standard for	ı
has made requests of (b) (6) to retract the reports/articles on the	
Study, but these requests have been denied.	
• (b) (6) filed a complaint with the EPA OIG, making charges that the (b) (6) authors engaged	
in research misconduct and plagiarism. The OIG found that the allegations raised did not fall	
within the scope of complaints that the OIG investigates. Therefore, the OIG referred the matter	r
to the ScIO, to evaluate the allegations for any loss of scientific integrity.	
According to (6)	
a member of the (b) (6)	
• "the (b) (6) planned, conducted and reported over an 8-year period (1983-	
1991) is the most robust study conducted to date of the short-term cardiac effects of brief	
exposure of human subjects to CO."	
• "in retrospect the (b) (6) did have some 'warts and blemishes.' However, I think the core findings of the study remain sound."	
According to (b) (6)	
According to (D) (O)	
Was carefully planned;	
<ul> <li>Had the goal: "to investigate the effect of exposure to at levels producing 2% and 4% COHB2,</li> </ul>	
on an objective indicator of myocardial ischemia, the time to onset of ST-segment changes in the	
exposure on time to angina pectoris, a symptomatic indicator of myocardial	
ischemia, was also evaluated";	
thas darried out with extraordinary tare at every step;	
• Was approved by IRBs at each of the 3 centers (b) (6)	
<ul> <li>Was the subject of detailed audits throughout the course of the study;</li> </ul>	
Was peer reviewed by (b) (6)      a multi-disciplinary group of scientists not	
involved in conducting or overseeing the research;	
<ul> <li>Was the subject of a supplemental technical review panel convened by (b) (6) that included 11 experts</li> </ul>	
in cardiology, biostatistics, clinical trials, and other relevant disciplines and was chaired by	
(b) (6)	
(b) (6)	
• Had its peer review results reviewed by the full (b) (6) which prepared a	
detailed commentary on the study;	
• Was the subject of a detailed (b) (6)	
United States Court of Appeals, for the District of Columbia Circuit, Argued September 26, 2013; Decided April 11, 2014; No. 11-1423	
http://www.cadc.uscourts.gov/internet/opinions.nsf/62426A01995956F285257CB700516276/\$file/11-1423-	
148/915.pdf	
Memorandum, dated February 23, 2015, from (b) (6)  Regarding Comments on Your	
Information in the next three paragraphs comes from a letter dated June 30, 2014, from (b) (6)	
President of (6) (6)	
request for intermediate the many (b) (6)	
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Was the subject of peer reviewed journal articles (b) (6) published by Study investigators; Was subjected to further review by 3 separate review panels convened by the EPA CASAC, an independent scientific body established in the CAA to scrutinize the scientific basis for all EPA decisions on NAAQS; and, Was planned, conducted, and reviewed by a large and institutionally dispersed number of individuals with no known incentive or motivation for research misconduct or for overlooking any evidence of research misconduct. speaking on behalf of <sup>(b) (6)</sup>also stated in his letter that (b) (6) plagiarism have no evident basis and, indeed, the cited publications were authored by the same investigators and are appropriately cross-referenced in the publications." oncluded that it did not see any reason to retract the Study's research report. The allegations and informed Directors concurred with (b) (6) assessment of (b) (6) decision to not retract the research report. May 19, 2014, letter. They reviewed 🚺 found no basis for (b) (6) allegations. Allegations regarding Human Subjects Research also reviewed ( allegations, including Appendices A through G. (b) (6) ound no basis for claims of unethical practices (e.g., researchers should have adhered to common rule standards, but acknowledges that the study pre-dates that regulation). (6) also disagreed with (b) (6) claims that the study's peer-reviewed, published tables and figures are wrong or misleading (e.g., 10) (6) cited errors in (10) May 19, 2014, letter). Dr. Grifo also asked o review convened a human subjects allegations of human subjects violations. (b) (6) summarized the committee's determination in a letter dated research ad hoc committee. (b) (6) June 10, 2015, to Dr. Grifo. The committee's review focused on (6) allegations of harm caused studies. According to (6) to human subjects who participated in the committee considered these allegations and the accompanying documentation in light of the prevailing ethical standards of the time, reflected both in regulation and in standard practice for the conduct and reporting of research involving human subjects. After careful review and discussion, it is the determination of this committee that there is insufficient evidence to conclude that participants in these studies suffered any harm, or were exposed to unreasonable risk for a study of this kind..." Conclusion of Review of Allegations regarding Human Subjects Research The human subjects research ad hoc committee convened by to review 🚺 allegations of violations of human subjects research requirements found that his allegations have no basis.

## Allegations regarding Plagiarism

The Scientific Integrity Review panel should focus on the allegations not related to research misconduct
(which is within the OIG's purview) or to human subjects research (the purview of (b) (6)
ad hoc committee). (6) allegations regarding a loss of scientific integrity relate to claims of
plagiarism and authorship issues.
(b) (6) in Appendix B to his May 19, 2015, letter to the Editors-in-Chief of (b) (6) and the President of the (b) (6) states that the authors of the (b) (6) are guilty of:
Failure to acknowledge supporting studies
o In the (b) (6) the Study authors failed to thank or give credit for (b) (6)
measurements in supporting studies from the (b) (6) Note, however, that
according to (b) (6) "the collaboration did not last long because the two labs coul
not reproduce each other'sresults."  O Data from the supporting studies was not included in the (b) (6) article
Data from the supporting studies was not included in the was article     Failure to acknowledge preliminary or pilot studies
o Including one in (b) (6) Appendix P
Republishing over 90% of the logical version verbatim in the EHP article. In contrast, only a few
passages in the (b) (6) article were copied verbatim from the (b) (6)
o (b) (6) in Appendix B, says that:
"According to (b) (6) the re-publication was arranged with
(b) (6) so the findings could be cited by EPA and the
review then getting underway (personal communication 2013). The (b) (6) at the
time was chaired by (b) (6) [sic] who, like (b) (6) was also a member of
the (b) (6) sic did not recuse himself from discussing or
voting on the questions about the (b) (6) tudy that EPA put to the (b) (6) in 1991."  o (b) (6) In his letter dated February 23, 2015, to (b) (6) Isaid, "Using your
very narrow interpretation of plagiarism, essentially every scientist who has ever
submitted a required progress or final report to a government agency and published the
same material in peer-reviewed papers would be viewed as guilty of 'plagiarism.'
Rubbish!"
Irregularities concerning guest and ghost authorship issues
o (b) (6) claims that (b) (6) should not have
been listed among the (b) (6)
their contributions were minimal.
says that the (b) (6) nembers should have been listed as coauthors,
since they oversaw the Study. They are identified as "Advisory Committee" in the
(b) (6) and the (b) (6) and in the acknowledgement section of the (b) (6)  o (b) (6) lists "major participants" and does not explain why they are not listed as
coauthors.
(b) (6) is listed as an author in the (b) (6) but not elsewhere.
(b) (6) has alleged research misconduct and plagiarism related to the
The OIG reviewed (b) (6) allegation in terms of research misconduct, found that the allegation

did not rise to the level of criminal charges, and referred the case to the EPA ScIO.

The EPA Scientific Integrity Review Panel should focus its review of (b) (6) allegations on those related to a loss of scientific integrity.

The EPA Scientific Integrity Policy cannot be applied retroactively to actions committed before the Policy was published (i.e., before February 2012). The actions that are the basis for (b) (6) concerns took place primarily in the 1980s and 1990s. Therefore, the Policy does not apply to those actions.

Nevertheless, the Scientific Integrity program office reviewed (b) (6) claims of a loss of scientific integrity, namely that the authors were guilty of plagiarism and other misdeeds related to authorship issues. (b) (6) main argument related to allegations of self-plagiarism is that the authors included sections of material from the (b) (6) However, (b) (6) says that, according to his personal communication with (b) (6) in 2013, the re-publication was arranged with so that EPA and the (b) (6) would be able to cite the findings during the (b) (6) review, which was about to begin.

In addition, (b) (6) alleges that the list of Study authors included ghost and guest authors.

However, the Scientific Integrity program office could find no evidence to substantiate those claims.

## Conclusion of Scientific Integrity Program Office Review of Allegations regarding Plagiarism

The Scientific Integrity program office finds that none of (6) allegations regarding plagiarism are compelling and that the documentation does not support a claim of a loss of scientific integrity in terms of plagiarism.

#### **Overall Conclusion**

The Scientific Integrity program office find that (0) (6) allegations do not meet the three criteria for establishing a loss of scientific integrity.

Criteria to Establish a Loss of Scientific Integrity	Findings
A significant departure from accepted practices of the relevant scientific or scholarly community?	None identified
The actions causing the loss of integrity were committed intentionally, knowingly or recklessly?	No such actions identified
The allegation is proven by a preponderance of evidence?	No such evidence

The EPA Scientific Integrity program office and the human subjects research *ad hoc* committee have concluded that the allegation has no basis and, therefore, the Scientific Integrity program staff recommend that the Scientific Integrity Review Panel dismiss the allegation.